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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Application Number: 10/665,343

Filing Date: September 18, 2003

Appellant(s): DIEHL ET AL.

Kenneth Crimaldi

For Applicant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/26/10 appealing from the Office action mailed 10/23/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3 and 7-15 are pending. Claims 2 and 4-6 are cancelled.

(4) Status of Amendments after Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be reviewed on Appeal

The examiner disagrees on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken is being maintained by the examiner.

Appellant's statement about the grounds of rejection is incorrect.

Claims are rejected over Antoni-Zimmermann et al. (US Patent 6,361,788) and Appellants disclosure and not only on US Patent 6,361,788.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 6,361,788	Antoni-Zimmermann et al.	3-2002

Appellant's disclosure

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 7-15 rejected under 35 U.S.C. 103(a) as being unpatentable over ANTONI-ZIMMERMANN et al.[1] and Appellant's disclosures. See the entire document especially abstract of the invention, lines 3-67 in column 2; lines 1-67 in column 3; lines 1-67 in column 4; examples and claims of ANTONI-ZIMMERMANN and entire specification of the present invention especially [0001], [0002] and [0003].

ANTONI-ZIMMERMANN teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances which embraces Appellant's claimed invention. The reference teaches a biocide composition that is improved in its components interact synergistically and therefore can be used in lower concentrations when used simultaneously, compared to the concentrations necessary in the case of the individual components. Thus, humans and the environment are exposed to less pollution and the costs of controlling harmful

[1] US Patent 6,361,788

microorganisms are reduced (lines 3-9, column 2). The reference teaches that this object is achieved by the invention by means of a biocide composition having at least two active biocidal substances, one of which is 2-methylisothiazolin-3-one (lines 10-16, column 2). The reference further teaches that biocide composition of the invention has the advantage that it can replace active substances used until now in practice, but suffering from disadvantages with respect to health and the environment, e.g., 5-chloro-2-methylisothiazolin-3-one (see lines 3-41 in column 2 and lines 33-38 in column 4). Moreover, the biocide composition of the invention can be produced with water as a favorable medium, if necessary. The addition of emulsifiers, organic solvents, and/or stabilizers is thus not necessary. Moreover the invention makes it possible to match the composition to specific goals by adding further active substances, for example, in the sense of an increased biocidal activity, improved long-term protection of the substances infected by microorganisms, improved compatibility with the substances to be protected, or improved toxicological or ecotoxicological behavior (lines 21-32, column 2 and lines 49-54, column 4).

In the biocide composition the 2-methylisothiazolin-3-one and the 1,2-benzisothiazolin-3-one are present in a total concentration of preferably 0.5 to 50%

by wt, in particular 1 to 20% by wt, particularly preferred 2.5 to 10% by wt, in each case relative to the total biocide composition.

The reference further teaches that the biocide composition of the invention can be used in very different fields. It is suitable, for example, for use in paints, plasters, lignosulfonates, chalk suspensions, adhesives, photochemicals, casein-containing products, starch-containing products, bituminous emulsions, surfactant solutions, motor fuels, cleaning agents, cosmetic products, water circulating systems, polymer dispersions, and cooling lubricants, against attack by, for example, bacteria, filamentous fungi, yeasts, and algae. The reference teaches a list of some active biocidal compounds, which includes presently claimed biocidal compound such as benzyl alcohol, (claim 8), sorbic acid, benzoic acid, phenoxy ethanol, (claim 1) and many others. See columns 3 and 4.

Specification discloses that all the compounds are well known biocides, see the entire document especially pages 1 and 2 where it teaches that the compounds used for the combination is known.

Instant claims differ from the reference in claiming synergistic combination in specific ratios of the components.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions for inhibiting synergistically the growth of microorganisms by using the teachings of the prior art to combine 2-methylisothiazoline and one or two active biocidal component. The ratio of the two components to find the synergism is a routine expectation for the one who is skilled in the art because the biocide composition of the reference teaches combination of at least two active biocidal substances, one of which is 2-methylisothiazolin-3-one. The composition can contain one or more other active biocidal substances selected according to the field of application. Specific examples are listed in the columns 3 and 4.

Present invention does mention only one biocide 2-methyl-3-isothiazolone; however, the term "comprising" allows other components to be added. Other biocides listed in column 3 and 4 include the compounds which are presently claimed. The combination with zinc pyrithione and climbazole is not mentioned specifically in the prior art however, Appellants specification discloses that all the biocides are commercially available. All the compounds are individually known as biocides. The reference teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances. Therefore, using

2-methyl-3 isothiazolone for synergism would have been obvious to one skilled in the art at the time the invention was made.

The motivation to prepare synergistic biocidal compositions and method of inhibiting microorganisms as presently claimed has been provided by the prior art (lines 49-67, column 4, lines 66, 67 in column 2 through lines 1-67 in column 3 and lines 1-7 in column 4, examples and tables).

The discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. Synergism is one factor to be considered in the ultimate determination of obviousness of the composition.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the

scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

See In re Kollman, 595 F.2d 48, 201 USPQ 193 (CCPA 1979) (Claims directed to a synergistic herbicidal composition comprising mixtures of an herbicide known as "FENAC" with a diphenyl ether herbicide in certain relative proportions were rejected as prima facie obvious. Appellant presented evidence alleging unexpected results testing three species of diphenyl ether herbicides over limited relative proportion ranges. The court held that the limited number of species exemplified did not provide an adequate basis for concluding that similar results would be obtained for the other diphenyl ether herbicides within the scope of the generic claims.

See Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) where it was held that "Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be

capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

"There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

"Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973); In re Klosak , 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid,

there is no evidence that the differences are unexpected. In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); In re Longi , 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); In re Freeman, supra".

In absence of any criticality and/or unexpected results presently claimed invention would have been prima facie obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Data in the Specification

The data presented in the specification covers the combination of 2-isothiazole and benzoic acid (Table 1), citric acid (Table 2), sorbic acid (Table 3), 1,2-dibromo-2,4 dicyclobutane (Table 4), 1,3-dimethylol-5,5-dimethylhydantion (Table 5), phenoxyethanol (Table 6), zinc pyrithione (Table 7), climbazole (Table 8), and benzyl alcohol (Table 9). The data presented is for certain organisms.

Claims are not limited to those organisms. The data does not commensurate with the scope of the claims. Further, the synergistic combinations have been taught by the prior art (lines 33-67, column 4, examples 1-21) and all the tables. Furthermore, the synergism as claimed would have been expected for reasons cited

above. The discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. Synergism is one factor to be considered in the ultimate determination of obviousness of the composition.

(10) Response to Argument

The rejection on record was made over US Patent 6,361,788 to Antoni-Zimmermann et al. and Applicant's own disclosure and not only on US Patent 6,361,788 as has been said in the first two lines of "arguments". A correction is requested.

The board had affirmed this case[2] earlier in 2008.

Appellants argue that they have demonstrated that their claimed biocide combinations display synergistic activity (synergistic activity < 1) within claimed ranges of biocide ratios. Examiner disagrees.

Appellants argue that "obviousness may be rebutted by demonstrating unexpected results relative to the prior art disclosure" and refer to In re Woodruff, 919, F.2d 1575, 1578 (Fed. Cir.1990). Examiner agrees.

It has been decided by court that "Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art----It is

well settled that a prima facie case of obviousness may be rebutted 'where the results of optimizing a variable, which was known to be result effective (are) unexpectedly good.'" In re Boesch, 617 F.2d 272, 276 (1980 C.C.P.A.), (quoting In re Antonie, 559 F .2d 618 (CCPA 1977). It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. See In re Kerkhoven, 205 USPQ 1069.

Antoni-Zimmerman teaches 2-methylisooxathiazoline-3-one (MIT[2]) including phenyl ethyl alcohol, sorbic acid, citric acid, benzoic acid and 1, 2, dibromo-2,4-dicyanobutane and does not teach the specific ratios of MIT to these second components claimed.

Present specification discloses that when sum of the Qa/QA and Qb/QB is greater than one, antagonism is indicated. When sum is equal to one, additive is indicated, and when less than one, synergism is demonstrated, the lower the **SI**, the greater the synergy shown by a particular mixture (Spec. 10, 1.22 through 11, 1.7).

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[2] BPAI--Appeal 2008-5426, Affirmed: decided on November 21, 2008. After the decision Appellant's filed RCE on

Table I and 3-8 of Appellant's specification include many results that are said to indicate synergism at specific ratios and for specific microorganisms with the claimed components.

An SI value of less than 1.00 is said to indicate synergism, while an SI value of 1.00 or greater is said to indicate no synergism, (Spec. 11, II. 4-7).

It is important to note that the specification in Tables 2 and 9 reports the results with second components not recited in Appellants claim 1.

Examiner believes that since all the biocides are known it would have been obvious to one skilled in the art to find out which combination will be good for certain organism. It would be just a routine experimentation. Due to the different biological metabolism and conditions of the organism, the combination of the two biocides will not produce the exactly the same results under any known circumstances. It would be expected that some combination of biocides with be better for one organism than the other. There is no new concept or invention which is considered unobvious or unexpected over the prior art.

The reference does not disclose combinations comprising 2-methyI-3"isothiazolone and zinc pyrithione, climbazole or citric acid, as recited in claims

7, 8 and 11, respectively. Citric acid has been disclosed in the present specification as known biocide (see last two lines in [0002]. The combination with zinc pyrithione and climbazole is not mentioned specifically in the prior art however, Appellants specification discloses that all the biocides are commercially available [0003]. All the compounds are individually known as biocides. The reference teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances. Therefore, using 2-methyl-3 isothiazolone for synergism would have been obvious to one skilled in the art at the time invention was made.

The question is that whether or not the present invention would have been obvious at the time the invention was filed. One skilled in the art would have been able to prepare the combinations as claimed at the time the invention was filed because the any skilled in the art would expect that the when two active compounds which are known to have synergic results can be combined in various ratios, some of them may be synergistic some of them may not be synergistic. It is an experimental observation and out of testing various combinations at different concentrations one can collect the data in the laboratory. The reference teaches that the synergistic combination of 2-methylisothiazolin-3-one and various other

active biocidal substances is improved in its components and interact synergistically and therefore can be used in lower concentrations when used simultaneously, compared to the concentrations necessary in the case of the individual components. Thus, humans and the environment are exposed to less pollution and the costs of controlling harmful microorganisms are reduced. This object is achieved by the prior art by means of a biocide composition having at least two active biocidal substances, one of which is 2-methylisothiazolin-3-one. The reference further teaches that biocide composition of the invention has the advantage that it can replace active substances used until now in practice but suffering from disadvantages with respect to health and the environment, e.g., 5-chloro-2-methylisothiazolin-3-one. The reference teaches the disadvantages of halogenated isothiazolone due to health and environment. It would have been obvious to one skilled in the art not use halogenated compound and be motivated to use halogen free isothiazoline as has been taught.

Since the reference excludes halogenated isothiazoline and explains the disadvantages, the phrase "substantially free from halogen" in claims does not make the composition unobvious over the prior art.

Applicant argues about Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992), that in "any particular combination, and therefore any synergistic biocide combinations and ranges discovered by such testing could not have been expected. Every invention requires testing, so to say that any testing, that might lead to discovery of unexpected, previously unknown effects are "routine experimentation," and that the results of such testing would have been expected.

Appellant argues that there are important differences between the factual situation in Quadranti and that in the present application. Appellant argues that in the present application, the SI values are calculated from minimum inhibitory concentration (MIC) of each component, which "is the concentration tested under a specific set of conditions that prevents the growth of added microorganisms" (see specification page 9, lines 19-20). Therefore, each SI represents a combination of biocides actually prevents growth of microorganisms. Similarly Appellants argue about In re Kollman (595 F.2d 48 (C.C.P.A. 1979)).

The basis of all the arguments in this regard is the testing method. The issue here is the data and the synergism of the combination of known biocides and not on the methods how the synergism was tested. In actual examples data does not commensurate with the scope of the claimed invention.

It has been decided by the Courts that "when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742. In the present case composition of the combination of known biocides as claimed would have been obvious to one skilled in the art at the time the invention was made for the reasons cited above.

Declaration

Declaration filed on 01/23/2009 and 6/19/2009 by Eileen F. Warwick has been considered.

Declaration filed on 01/23/2009

The declaration explains the invention that some of the data is not synergistic against certain organisms. The declaration shows that the combination as claimed cannot be predicted for synergistic activity on every organism. The reason is the same as has been argued by the examiner. Claims are not limited to those organisms. The data does not commensurate with the scope of the claims. The synergistic combinations have been taught by the prior art (lines 33-67, column 4, examples 1-21) and all the tables. Furthermore, the synergism as claimed would have been expected for reasons cited above. The discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. Synergism is one factor to be considered in the ultimate determination of obviousness of the composition.

Declaration filed on 06/19/2009

The declaration discloses that some biocides do not show any synergism. The claimed combinations are disclosed by Antoni-Zimmermann et al so there is no possibility that claimed combination will have no synergy. It would have been expected that some of the biocide combination may be synergistic some may not

be synergistic. Since the synergistic combinations have been taught by the prior art (lines 33-67, column 4, examples 1-21) and all the tables the claimed invention is considered obvious. Claimed compounds are disclosed in prior art as has been discussed in detail.

For the claimed compositions Appellants contend did exhibit synergism. Appellants have not supplied supportive evidence, one Skilled in the art sufficient to show that unexpected synergism was demonstrated. See Huellmantel, 324 F. 2d at 1003. Furthermore, the data does not commensurate with the scope of claims. The specific concentrations have been tested on few organisms and claims includes any organism.

> Tables 1 and 3-8 report what are said to be synergistic effects for many of Appellants' claimed compositions. However, the tables also demonstrate that Appellants' claimed ranges of combinations are not synergistic, according to Appellants' criteria, across the entire range of ratios claimed for all microorganisms tested. (FF 7). Appellants report a "synergism index" or SI value to demonstrate synergy. (FF 4). SI values of

> less than 1.00 indicate synergy, while those equal to or greater than 1.00 do not. (FF 6). For example, Table 1 reports the effects of the combination of MIT and benzoic acid, which are claimed at a range of ratios between 1/0.13 and 1/67. When MIT and benzoic acid at a ratio of 1/50 was tested on *A. niger*, the SI value was 1.67 – indicating no synergism. (FF 7). When MIT and benzoic acid at a ratio of 1/16 was tested on *C. albicans*, the SI value was 1.03 – indicating no synergism. (*See id.*). Table 3 reports the effects of the combination of MIT and sorbic acid, which are claimed at a range of ratios between 1/4 and 1/133. When MIT and sorbic acid at ratios of 1/10, 1/13, 1/24, 1/30, and 1/40 were tested on *A. niger*, the SI value was equal to or greater than 1.00 – indicating no synergism. (*See id.*). Similar examples of nonsynergistic, claimed ratios were found in each table. (*See id.*). Thus, Appellants' own results show that the entire claimed range does not demonstrate an SI value said to indicate synergy and that such synergy does not occur with every microorganism. These gaps in the reported synergy raise significant doubt about whether those of skill in the art would have found the specifically claimed combinations to be unexpectedly better than the combinations taught by Antoni-Zimmermann.

Appellants have not shown that the claimed combinations of first component and second components, in the claimed ratios, demonstrate unexpected results in terms of an unexpected synergy for the entire scope of the claims. The data does not commensurate with the scope of the claims. Further, the synergistic

combinations have been taught by the prior art (lines 33-67, column 4, examples 1-21 and all the tables.

Appellants argue that showing unexpected results for the claimed combination by showing synergism is not obvious. However, the "Synergism is one of the factors to be considered in the ultimate determination of obviousness of the composition. However, we attribute no magic status to synergism per se since it can be expected or unexpected." See In re Huellmantel, 324 F. 2d 998, 1003 (CCPA) 1963). See also In re Diamond, 360 F. 2d 214, 218 (CCPA 1966).

Like a showing of any unexpected result, a showing of an unexpected synergism "must be commensurate in scope with the claims which the evidence is offered to support" to be persuasive. Cf. In re Grasselli, 713 F. 2d 731, 743 (Fed. Cir. 1983) (quoting 448 F. 2d 791 (CCPA 1971).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sabiha Qazi/

Sabiha Qazi, Ph.D.

(Primary Examiner, Art Unit 1628)

Conferees:

/Brandon J Fetterolf/

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